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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,129

02/27/2006

Ian Richard Catchpole

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06/08/2009

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

06/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/538,129	Applicant(s) CATCHPOLE, IAN RICHARD	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/6/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Applicant's preliminary amendment filed June 6, 2005 is acknowledged and has been entered. Claim 3 has been amended. Claims 1-5 are now pending in the instant application.

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see p. 22, l. 24). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. The disclosure is objected to because of the following informalities: there is no brief description of the drawings section found in the specification. With regard to PTOCpG3 on page 25, line 11 and page 26, line 6 is this SEQ ID NO: 4 or is it SEQ ID NO: 20? The amendment to the specification on September 24, 2008 made corrections such that PTOCpG3 is now SEQ ID NO: 20 (see page 23, lines 18-19 and page 25, line 5). Appropriate correction is required.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 is vague and indefinite in the recitation of "wherein the sequence...". Which sequence in claim 1 does Applicant intend for SEQ ID NO: 3, 14, 18 or 20 to represent? It is noted that SEQ ID NO: 14, 18 and 20 are different from oligonucleotide set forth in claim 1. With regard to claims 1-3, is SEQ ID NO: 2 the LNA? Claim 5 is vague and indefinite in the recitation of "sufficiently low"; what are the metes and bound of "sufficiently low"? What does Applicant intend?

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Braasch et al (Chemistry & Biology, 2001, 8:1-7).

Braasch et al discloses oligonucleotides comprising locked nucleic acids as well as CpG oligonucleotides (abstract Table 3) and that these oligonucleotides have been synthesized (see p. 1). Braasch et al discloses that use of

phosphorothioate linkages can reduce the target selectivity of oligonucleotides by increasing binding to proteins, but this enhanced binding also improves pharmacokinetic properties (p. 5). Braasch et al discloses that "The high affinity of hybridization demonstrated by pure LNA oligomers may allow improvement of DNA array technology and DNA diagnostics. Not only do LNAs offer the potential for high affinity binding, but the fact that their synthesis and physical properties closely resemble those for DNA means that existing protocols for creating arrays will need only minimal adjustment. In the only study reported to date, Orum et al. have immobilized LNAs complementary to the Factor V Leiden mutation to individual wells of a microtiter plate (citation omitted). They then developed a 1-h enzyme-linked immunosorbent-type assay capable of discriminating between amplified DNA from Factor V homozygotes, heterozygotes and unaffected individuals." (p. 6) Braasch et al disclose that LNAs have the potential to be improved agents for oligonucleotide arrays and in vivo repression of gene expression. Advantages include low toxicity, the ability to make LNA-DNA chimeras, nuclease resistance synthesis by standard methods and availability from a commercial supplier." (pp. 6-7) Braasch et al discloses methods of synthesizing or manufacturing a LNA-CpG conjugate and therefor anticipates the claimed invention.

8. No claims are allowed.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N. M. Minnifield
Primary Examiner
Art Unit 1645

/N. M. Minnifield/

Primary Examiner, Art Unit 1645

June 2, 2009